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A retrospective review of breast reconstruction outcomes comparing AlloDerm and DermaCELL

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ABSTRACT

Acellular dermal matrix (ADM) has become an accepted and advantageous adjunct to alloplastic breast reconstruction. The increase in demand has led to an upsurge of dermal-based products, both human and animal derived. There are few direct ADM comparative studies, but it is unclear whether there are any differences in complication rates. Our primary objective was to determine whether there is a difference in outcomes between AlloDerm and DermaCELL in immediate alloplastic breast reconstruction.

A retrospective chart review of those who underwent immediate alloplastic breast reconstruction from January to December 2016 was performed. This encompassed 64 consecutive patients (95 breasts) with tissue expander or direct-to-implant reconstruction and either AlloDerm or DermaCELL ADM. Demographics, particulars of the surgery, additional treatments and complications were all recorded. Differences in seroma, haematoma and infection rates, as well as more serious complications including implant replacement, capsular contracture and failure, were all reviewed.

The groups were comparable in terms of age, BMI and relevant comorbidities. Mastectomy weight and resulting implant volume were higher in the DermaCELL group, with volume reaching statistical significance ($p = 0.001$). With an average follow-up of 18 months, there was no difference in capsular contraction or implant

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replacement. However, in those who developed capsular contracture in the DermACELL group, more breasts had no history of radiation, which was significant ($p=0.042$). Overall, there were no significant differences in complication rates of seroma, haematoma, mastectomy flap necrosis and infection.

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Introduction

Alloplastic breast reconstruction is on the rise with a yearly increase of 11% in the last 10 years in the US.¹ Since 2002, the number of implant reconstructions has now surpassed the number of autologous reconstructions.¹ Acellular dermal matrices (ADMs) were introduced after approval in Canada in 2009.² Under European legislation, human-derived ADMs manufactured outside the EU cannot receive a CE mark. To date, only one human-derived ADM manufactured in Europe has undergone prospective assessment under licence.³ Human-derived ADMs are otherwise not widely available in Europe for breast reconstruction. ADMs, used as an inferior sling in conjunction with sub-pectoral implants or tissue expanders, provide extra coverage allowing for higher operative fill volumes, direct-to-implant reconstruction and superior cosmetic results.^{4–6} Because of advancing financial burden on the health-care system, a cheaper alternative is sought. Animal-derived ADMs have been produced; however, Paprottka et al. found a higher incidence of complications and concluded that where possible, human-derived products should be used in preference.⁷

AlloDerm was among the first of the human-derived ADMs, and there is a plethora of evidence to support its safety in breast reconstruction.^{8–10} Given its success and market domination, the industry has expanded, and multiple alternatives are currently available. Potential benefits include reduced cost, increased vascular ingrowth, shorter time to drain removal and potentially lower seroma rates.^{8,11,12} DermACELL is a newer ADM and have limited, but promising, data to support a similar complication profile as that of the AlloDerm.^{12–15}

The most common complications associated with ADM breast reconstruction are haematoma, seroma and infection.¹⁶ Pooled data from a systematic review of 16 selected studies with ADM reconstruction quoted rates of 2%, 5.7% and 6.9% for cellulitis, infection and seroma, respectively.¹⁷ Devastating events such as reconstructive failure have been reported in 5.1%.¹⁷ Radiation, larger breasts, higher intraoperative fill volumes and increased surface area of ADM are all independent risk factors for adverse outcomes.¹⁸ In addition to these risk factors, elevated body mass index (BMI) and smokers are also at higher risk.¹⁹

Given the lack of comparative data, we opted to review outcomes in two similar reconstructive groups treated with different ADMs: AlloDerm and DermACELL. The primary objective was to evaluate safety and complication rates and assess whether the products are comparable.

Materials and methods

A retrospective review of 64 consecutive patients was conducted after approval from the University of British Columbia Clinical Research Ethics Board (Feb 2018, H17-02916). All patients with ADM inserted for immediate breast reconstruction from January to December 2016 were identified. Tissue expander and direct-to-implant reconstructions were included, but augmentations, revision mastectomies and congenital reconstructions were excluded. A single delayed reconstruction was included, as the primary operation was an immediate reconstruction, with mastectomy on the contralateral side. The surgeon had 7 years of experience using AlloDerm and 6 months with DermACELL before the start date of the review.

Table 1
Demographics.

Demographics (N = number of patients)	AlloDERM N=28	DermACELL N=36	p value
Age, years			
Mean +/- SD	52.4 ± 10.9	53.1 ± 11.5	0.81
Body mass index, kg/m²			
Mean +/- SD	24.3 ± 5.8	24.9 ± 5.1	0.65
Diabetic (%)	1 (3.6)	0	0.260
Genetic predisposition:			
BRCA gene (%)	1 (3.6)	2 (5.7)	0.70
Mental health (%)	8 (28.6)	6 (17.1)	0.28
Autoimmune disease (%)	2 (7.1)	1 (2.9)	0.427
Smokers (%)	0	0	–
Follow-up (days ± SD)	517.6 ± 254.1	569.0 ± 199.7	0.547

Eight different general surgeons performed mastectomies for oncological or prophylactic and were either unilateral or bilateral. Mastectomy incision pattern and nipple preservation was a joint decision made by the surgeons. The implant pocket was defined with elevation of the pectoralis major muscle, and the ADM (8 × 16 cm, unfenestrated) was anchored to the inframammary fold (IMF) with braided suture. An antibiotic solution (cefazolin/gentamicin) was used to irrigate both the pocket and the implant. The implant or partially filled tissue expander was placed under the elevated pectoralis major muscle and the free muscle edge secured to the ADM. A single drain was placed superficial to the ADM. Once the mastectomy skin was closed, the vascularity of the skin flap was assessed clinically. Nitroglycerin paste was applied to the mastectomy flaps on the basis of published evidence from our institution that showed a significant reduction in mastectomy flap necrosis.²⁰ Follow-up consisted of outpatient visits on weeks 1 and 2, and if wounds were satisfactory, expansion began at week 2. Drains were typically removed on day 7 or when drainage was <30 ml in 24 h. If radiotherapy was deemed to be required preoperatively, then a tissue expander was placed. However, the decision was ultimately determined by the eventual pathology.

All digital and physical notes, operative and pathology reports were reviewed. Patient demographics and breast characteristics of each group were collected and compared. Each reconstructed breast was evaluated and analysed independently for complications. Infection was defined as cellulitis, purulent discharge or systemic illness. Seromas were defined clinically by physical examination and treatment depended on size. Given the follow-up of 18 months, data on capsular contracture and implant replacement were also collected.

Statistical analysis was performed with IBM® SPSS® Version 25. Shapiro–Wilk test was performed to assess whether continuous data were normally distributed, and based on this, independent t or Mann–Whitney *U* test was performed. Dichotomous variables such as radiation or complications were assessed with chi-square analysis. Counts and percentages were used for categorical values, and *p* values < 0.05 were deemed to be significant.

Results

Sixty-four cases were reconstructed with ADM from January to December 2016. This equated to 39 breast reconstructions in 28 patients with AlloDerm and 56 breasts in 36 patients with DermACELL. The two groups were similar with regard to known risk factors, age, BMI, diabetic and smoking history. Similarly, there was no difference in treatment with radiotherapy or chemotherapy. A summary of the patient demographics is given in [Table 1](#).

[Table 2](#) presents operative details and breast characteristics. There were more bilateral reconstructions in the DermACELL group; however, this did not reach significance (*p* = 0.314). One case had a different ADM used in each breast but was analysed as a bilateral reconstruction. The number of nipple- or skin-sparing mastectomies was also similar in both groups (*p* = 0.231). Wise skin pattern resection featured more in the DermACELL cohort but did not reach significance (*p* = 0.051). However,

Table 2
Breast characteristics.

Breasts reconstructed with an ADM	AlloDerm N= 39	DermACELL N= 56	p value
Additional balancing contralateral procedures (%)	7 (18.4)	10 (18.2)	0.977
> Reduction	1	3	
> Mastopexy	2	4	
> Implant	4	3	
Unilateral Mastectomy (%)	16 (57.1)	15 (41.7)	0.314
Bilateral Mastectomy (%)	12 (42.9) ^a	21 (58.3) ^a	
Mastectomy details (%)			
> Nipple sparing	9 (23.1)	19 (34.5)	0.231
> Skin sparing	30 (76.9)	37 (65.5)	
Skin pattern (%)			
> Wise pattern	13 (33.3)	30 (53.6)	0.051
> Non-wise pattern	26 (66.7)	26 (46.4)	
Reason for mastectomy (%)			
> Malignancy	27 (69.2)	37 (67.30)	0.841
> Prophylactic	12 (30.8)	18 (32.7)	
> Delayed contralateral	0	1 (1.8)	0.397
Breast cup size (%)			
> A–C	20 (51.3)	17 (30.4)	
> ≥C	19 (48.7)	39 (69.6)	0.033
Mean mastectomy weight (grams + SD)	444.5 ± 329	488.9 ± 262.8	0.242
Data unavailable	9	10	
Implant details			
> Direct to implant (%)	27 (71.1)	47 (83.9)	0.134
> Implant volume (cm ³ +SD)	315.56 ± 120.9	404.36 ± 126.69	0.001
> Tissue expander	11 (28.9)	9 (16.1)	0.134
Post-operative details			
> Radiation (% breast)	10 (25.6)	11 (19.6)	0.488
> Chemotherapy (% patient)	14 (50)	17 (47.2)	0.512
> Time to drain removal (days ± SD)	8.21 ± 2.28	7.83 ± 1.78	0.877

^a One bilateral reconstruction feature in both AlloDerm and DermACELL groups, as a different ADM was used in each breast.

there was a significant difference in breast size, with DermACELL having a larger breast size ($p=0.033$) and larger implant volumes ($p=0.001$).

Complications are listed in Table 3, and the overall rate per breast was 42%. Radiotherapy occurred in 22% of breasts and chemotherapy in 48% of patients. Radiotherapy unsurprisingly increased complication risk ($p=0.036$), in particular, capsular contracture ($p < 0.001$). Bilateral reconstruction increased the overall risk of complications ($p=0.025$) but not specifically seroma ($p=0.796$). Two of the eight general surgeons performed mastectomies in 39 of the 64 cases. Complication rates were significantly lower with the most regular surgeon ($p=0.026$). However, when comparing the two most frequent to the remaining surgeons, there was no significant difference in complication rate ($p=0.073$).

Hematomas occurred in 6 breasts (6.3%). The DermACELL group had two delayed hematomas discovered at 7 and 9 months: one after a fall, which resulted in implant rupture, and another discovered at surgery for capsular contracture. Both breasts subsequently required replacement of implants after capsular contracture developed. The DermACELL cohort had 8 infections compared to two in the AlloDerm group. One AlloDerm infection was delayed and post dental treatment but fortunately resolved with oral antibiotics alone. One DermACELL patient was thought to have red breast syndrome, as cultures were negative, erythema displayed no response to antibiotics and, eventually, was self-limiting.

The most serious complication of pulmonary embolism was diagnosed by CT at one week despite early mobilisation and mechanical thromboprophylaxis. She had a medical history of melanoma and bilateral breast cancer. Another patient developed a bowel obstruction, which resolved spontaneously.

A reconstructive failure occurred in each group. An AlloDerm bilateral reconstruction developed a small haematoma associated with bilateral MFN, which led to operative debridement. Subsequent breakdown and exposure resulted in extrusion of the left implant, and an expander had to be placed acutely. This too became exposed and was removed, but eventually, the reconstruction was completed

Table 3
Complications and management.

Patient number (N = Number of breasts)	AlloDerm N = 39	DermACELL N = 56	p value
Number of unplanned operations – mean per breast ± SD	0.231 ± 0.731	0.29 ± 0.54	0.161
Seroma	5 (8.9)	5 (7.1)	0.713
Office drainage	3	4	
Interventional radiology	1	1	
No intervention	1	0	
Mastectomy flap necrosis	4 (10.3)	4 (7.14)	0.591
Office treatment	1	3	
Operative	3	1	
Haematoma	3 (7.7)	3 (5.4)	0.645
Immediate	3	1	
Delayed (>30 days after surgery)	0	2	
Infection	2(3.6)	8 (11.4)	
Oral antibiotics	1	2	
IV antibiotics	1	2	0.105
Operative management	0	4 ^a	
Red Breast syndrome	0	1	
Capsular contracture	5(12.8)	7 (12.5)	0.963
Radiation	5	3	<0.001
Without radiation	0	5	0.042
With additional complication	2	4	
Implant removal	7 (17.1)	15 (27.8)	
Rupture	0	1	
Infection/exposure	0/1	4/0	0.221
Contracture	3	4	
Size	2	1	
Opportunity/repositioning	1	5	

^a One infection two years after treatment.

with an implant. One patient who had bilateral DermACELL reconstruction developed an acute infection in the left side, which required removal and, two years later, presented with infection of her right implant, which also resulted in explantation.

Overall, there were no significant differences in the complication rates that arose in the DermACELL and AlloDerm groups. Age, BMI, skin pattern type and mastectomy weight did not affect complication rates. The reason for mastectomy did not affect complication rates either ($p = 0.841$). A larger implant volume showed a trend for increasing complications but did not achieve significance ($p = 0.076$). It did, however, show a significant increase in risk for implant replacement ($p = 0.041$). Capsular contracture in patients without radiation was observed only in the DermACELL cohort ($p = 0.042$).

Discussion

Literature comparing products can be fraught with bias, including surgeon experience, different techniques and influence of the industry. This is a retrospective review with a relatively small number of cases but represents a single surgeon with a consistent practice over a 12-month period. Breast reconstruction starts with healthy mastectomy skin flaps, and different techniques have an impact on mastectomy flap survival. In this study, two general surgeons carried out 61% of the mastectomies. Comparison of complications between surgeons was difficult because of low numbers, but there was no difference with regard to complication rate when comparing these two surgeons to the rest of the group. One of the most frequent surgeons had the lowest complication rate, which reached significance ($p = 0.026$). This displays the importance of having a consistent team and good relationship with general surgery in breast reconstruction.

Experience was gained with both products before the study and will have minimal impact on results, as we believe the learning curve is steepest when learning the initial technique of ADM insertion. DermACELL is produced by an anionic detergent and undergoes a decellularisation process, removing more than 97% of all DNA, which is much higher than that of competitors, including Allo-

Derm.²¹ Low-dose gamma radiation is used for irradiation, and the product reaches a higher level of sterility (sterility assurance level 10⁻⁶). Makers of DermACELL technology promote that the processing and degree of sterility maintain biomechanical strength but allow for improved vascular ingrowth and reduction in immune responses. The main difference found by the senior surgeon was increased thickness and slight decreased pliability of DermACELL, but this did not alter the technique used.

There are few comparative studies reviewing DermACELL and AlloDerm, but Zenn et al. published a review of two surgeons transitioning from AlloDerm to DermACELL and found no difference in complication rates.¹⁵ Pitman et al. found similar outcomes but a trend towards lower seroma rates and reduction in time to drain removal with DermACELL.⁸

The two groups studied were similar in risk factors for complications. Overall rate was 42.0%, but 22% of breasts were exposed to radiation, and follow-up was on average 18 months. A similar study found 62 complications in 100 cases with a follow-up of only 90 days, and only 10% had radiation.⁸ Counting only acute (within 3 months) complications, 35 in 95 breasts had an adverse outcome in our study. Some literature reports rates as low as 11–12%, but these are studies of early (<60 days) complications, pooled results and not specifically direct-to-implant reconstructions.^{22,23} Vardanian, on the other hand, found a rate of nearly 33.5% with ADM use.⁵ Both the nature of the longer follow-up and documentation of all, even minor complications, increased our overall rate. One early complication often led to subsequent adverse events such as contracture or implant replacement. The most important finding was no difference in complication rates between the AlloDerm and DermACELL groups.

The DermACELL cohort had larger breasts, increased mastectomy weight and higher implant volumes. This likely led to the higher rate of Wise skin pattern resection, which is often used in large ptotic breasts. The Wise pattern itself has been associated with higher complication rates.²⁴ In our study, this pattern represented 45% of mastectomies but showed no increased risk of complications. A systematic review of Wise pattern in relation to direct-to-implant reconstruction had elevated complication rates in comparison to two-stage reconstruction.²⁵ Pooled figures found 30% for direct to implant compared to 20% for tissue expander use. In particular, rates of delayed wound healing, seroma and MFN were increased. In our study, the majority (78%) were direct to implant and Wise pattern resection, which pose higher risk, but both groups were affected.

Infection rate including cellulitis and periprosthetic collections were low with a combined average of 10.5%. More bilateral reconstruction with potentially longer operation times may have led to the slight increase seen within the DermACELL group. Overall, the AlloDerm rate of 3.6% is lower than that of 6% found by Pittman et al., but if cellulitis was included in their figures, their rate would be 10%. Our combined rate of 11.4% in DermACELL was higher than their rate of 4%.⁸ A larger review of more than 2000 ADM reconstructions revealed a pooled rate of nearly 5% for infection.²⁶

Corban et al. found that the Wise pattern with direct to implant had higher rates of MFN.²⁵ Our MFN rate was 8.4%, which is lower than the documented rates at our institution, but this will have been influenced by our use of nitroglycerin paste.²⁰ The MFN rates between DermACELL and AlloDerm did not significantly differ despite more Wise pattern and higher implant volumes in the DermACELL group. In addition, the majority of MFNs in the DermACELL group could be managed without operative debridement.

There was no significant difference in seroma rate between AlloDerm and DermACELL. Follow-up was performed in private consulting rooms where access to ultrasound is limited and would incur further cost and inconvenience. We acknowledge that ultrasound would be advantageous in not only qualifying but also quantifying the seroma, but it is not always practical. Our DermACELL seroma rates were lower than those of Bullocks et al. (22%)²⁷ but similar to Ortiz's rates of 8.3% in patients with malignancy. Post-operative radiotherapy increased this rate to 14.3%,¹⁴ and more than 20% of our breasts had radiotherapy. Parks et al. reviewed AlloDerm reconstructions in more than 500 patients and recorded seroma rates closer to 30%.²⁸ The senior surgeon routinely uses a single drain as does Bullocks,²⁷ but the others did not specify.^{14,28} Some authors would advocate for more than one drain to reduce seroma.^{13,29} Higher seroma rates have also been linked to bilateral breast reconstruction possibly due to disruption of the internal thoracic perforators.¹⁹ This was not replicated in our study, as bilateral reconstruction did not increase risk of seroma.

The practicalities of follow-up determined our drain removal, which was commonly at 7 days if the patient reported <30 ml in 24 h. We therefore are unable to replicate the reduction in drain duration with DermACELL, which has been previously published.^{8,13} Pittman et al. found AlloDerm to have a higher rate of red breast syndrome when not rinsed before insertion.⁸ This was not mirrored in our study, as there was only one case of suspected red breast syndrome, which was conversely found in a DermACELL patient.

The size, type and thickness of ADMs can be variable, and a larger surface area of ADM has been associated with higher complication rates.¹⁸ In this study, consistently sized pieces of ADM (8 × 16 cm) were used for all reconstructions. The ADMs were all unmeshed and rectangular in shape. There is some emerging evidence to support a possible reduction in the seroma with meshed ADM, but these products are not yet widely available, and further research is required.³⁰

Integration of ADM is essential in achieving neutral balance between graft and host. Lack of incorporation of the matrix leads to an imbalance, which could potentially contribute to increased mobility of the implant, which may result in seroma, inflammation and eventually capsular contracture. In a study, 7 days after surgery, DermACELL capsules had double the vascularity compared to that of AlloDerm.³¹ In another study, capsules were sampled from ADM and non-ADM areas and showed significant reduction in fibroblasts and inflammation with ADM.³² Two other studies have histological evidence of normal healing, reduced inflammation and incorporation of DermACELL.^{27,33} This study unfortunately was retrospective in nature, and therefore, we did not have histological evidence of capsules. It has been long known that capsular contraction occurs more frequently after radiation, which was demonstrated in our results, with more than half of capsular contractures having had radiation. However, surprisingly, in breasts displaying signs of contracture, five in the DermACELL group had no history of radiation compared to none in the AlloDerm group. Although small numbers, this is concerning, as, although we have an average of 18 months follow-up, contracture can develop much later. Given that there were a few additional infections in the DermACELL group, this may have contributed to the additional capsular contracture based on the biofilm theory.^{34,35}

Cost of ADMs is an important consideration, especially as British Columbia is the 3rd highest consumer in Canada.² DermACELL can be 15–35% less expensive, and therefore, the financial impact of this is considerable.¹⁵ With more ADMs proven as safe alternatives, an increase in competition may drive a reduction in cost.

Limitations of our study include the retrospective nature with relatively small numbers, and therefore, data should not be overinterpreted. The nature of retrospective studies was reflected in missing data and absence of histological proof of ADM incorporation. The groups had some minor differences, which is inevitable with a retrospective review. Even with a slightly higher risk profile (larger breasts, more Wise pattern and nipple-sparing mastectomies), the DermACELL group patients had no resulting increase in complications.

Our aim was to show that an alternative ADM had a similar safety profile as that of an established ADM, thus allowing for an expansion in choice. Countries in which AlloDerm is unobtainable or too expensive may now have confidence using a safe substitute. Large-scale prospective randomised trials would be invaluable to provide further comparisons between different human-derived ADMs.

Declaration of Competing Interest

Allergan provides an educational grant to help support a breast fellowship in the University of British Columbia.

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